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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,620	09/15/2000	Jay M. Short	DIVER1140-3	2110
29062	7590	06/02/2004	EXAMINER	
DIVERSA CORPORATION 4955 DIRECTORS PLACE SAN DIEGO, CA 92121			NASHED, NASHAAT T	
			ART UNIT	PAPER NUMBER

1652

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/663,620

Applicant(s)

SHORT, JAY M.

Examiner

Nashaat T. Nashed, Ph. D.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on the amendment filed 3/22/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 170-230 and 232-238 is/are pending in the application.
- 4a) Of the above claim(s) 172-174, 176-189, 202, 204-213 and 236 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 170, 171, 175, 190-201, 203, 214-230, 232-235, 237 and 238 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/11/04</u> . | 6) <input type="checkbox"/> Other: _____ |

The application has been amended as requested in the communications filed February 11, 2004 and March 22, 2004. Accordingly, claims 170, 224, 225, and 238 have been amended, and claim 231 has been canceled.

Claims 170, 171, 175, 190-201, 203, 214-230, 232-235, 237, and 238 are under consideration in this Office action.

The terminal disclaimers filed on February 11, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U. S. Patents 5,939,250, and 5,958,672 as well as any patent mature from copending application serial number 09/375,605 has been reviewed and is accepted. The terminal disclaimer has been recorded.

New Rejections:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 170, 171, 175, 190-201, 203, 214-230, 232-235, 237, and 238 are rejected under 35 U.S.C. 101 because they are directed to an inoperative method. The methods require a comparison step between an unidentified and characterized wild-type enzyme and a mutant enzyme isolated from a mutagenized library prepared from unselected DNA isolated from environmental sample.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 170, 171, 175, 190-201, 203, 214-230, 232-235, 237 and 238 are rejected under, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) Step (d) in claim 170 renders the claim indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired for the reasons set forth in the prior Office action. The claim does not contain a step to identify and characterize a protein having an activity of interest before the mutagenizing step. Thus, it is unclear to this examiner how such a comparison step can take place.

Applicants argue that the examiner has not met his burden and provided reasons for indefiniteness.

Applicants' arguments filed 2/11/04 have been fully considered but they are not deemed to be persuasive. In the previous Office action, the examiner provided sufficient reasoning as why the claim is considered indefinite. In fact any person with some proficiency in the English language would recognize the problem with the claim. Step (a) of the claimed method is directed to a screening step to identify the presence of an activity interest. It does not require any quantitative measurements of activity. Step (d) requires a comparison step between a wild-type enzyme and a mutant having desired characteristics. For example, in step (a) one of ordinary skill identifies a glycosidase activity as an activity of interest present in the library. The source of activity may be a single clone containing one or more coding sequence for glycosidase or multiple clones each of which harboring more than one coding sequence of glycosidase. In step (d) said ordinary skill in the art identifies a mutant of the glycosidase activity. The desired property of the mutant or mutants can't be compared because he/she would not know to what to compare it. The claimed method require additional step prior to mutagenizing the library step in which the wild-type members of the library are isolated and a desired property is characterized such as substrate specificity or thermal stability. Once such a step is carried out a comparison step is possible. Without isolating the wild-type enzyme comparison is not possible. Thus, the claim remains rejected.

- (b) The phrase "pooled prior to insertion into clones of the library" in claim 220 lacks antecedent bases in the claim from which it depend, and renders the claim indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired for the reasons. First, there is no embodiment of claim 170 directed to insertion of nucleic acid clones. Second, the act of pooling nucleic acid is a selection process, which directly negates an embodiment of claim 170, i. e., obtained without selection.
- (c) The limitation "wherein the library is generated from pooling individual gene libraries generated from the nucleic acid" in claim 221 renders the claim indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The act of pooling nucleic acid is a selection process, which directly negates an embodiment of claim 170, i. e., obtained without selection.

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Applicants argue that disclosure the examiner did not explain why the claim is indefinite.

Applicants' arguments filed 2/11/04 have been fully considered but they are not deemed to be persuasive. The above rejections (d) and (e) are copies of the rejections in the previous Office action, mailed August 13, 2003. Clearly, the rejection contains an explanation as why the claim is considered indefinite. Claim 220 is dependent from claim 170. The phrase "insertion into clones of the library" does not appear in claim 170 anywhere. Also, claim 221 is dependent from claim 170. It is not clear to this examiner the source of nucleic acid being pooled in claims 220 and 220. In order to pool nucleic acid, one must select fractions of nucleic acid to be pooled.

- (d) The phrases "the oligonucleotide labeled with a detectable molecule label" in claim 225 renders the claim indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. A probe/primer is an oligonucleotide labeled with a detectable moiety. Since the detectable moiety is always covalently attached to the oligonucleotide, the detectable moiety can't possibly be a "molecule".

Applicant has not traversed the rejection and amended the claim by inserted the word label after the molecule without deleting the word molecule. This rejection would be obviated when the word molecule is deleted.

- (e) Claim 232 recites the limitation "screen further desired bioactivity" in claim 170. There is insufficient antecedent basis for this limitation in the claim. Also, the phrase is confusing because of the role of a second "desired protein" to identify a first desired protein activity. Claim 232 is drawn to obtain single protein, i. e., modified protein having improved activity.

Applicants argue that the Office action does not provide any reasons for indefiniteness of the claim.

Applicants' arguments filed 2/11/04 have been fully considered but they are not deemed to be persuasive. The rejection statement above is a copy of the rejection from the Office action mailed August 8, 2003. The word indefinite does not appear anywhere. Claim 232 is dependent from claim 170 wherein the phrase bioactivity does not appear, i. e., lack of antecedent basis for this limitation. Again the claim is not clear whether the further activity belong to the same genus of activity as that of the first activity such as glycosidase, or different genus of activities such as glycosidase and protease.

New Rejection:

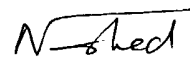
- (f) Step (f) in claim 238 renders the claim indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired for the reasons set forth in the prior Office action. The claim does not contain a step to identify and characterize a protein having an activity of interest before the mutagenizing step. Thus, it is unclear to this examiner how such a comparison step can take place.
- (g) Claims 171, 175, 190-201, 203, 214-219, 223, 226-230, 234, 235, and 237 are included in this rejection because they are dependent on rejected claims and do not correct the deficiencies of the claim from which they depend.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
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